

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Wolfenbarger, et al.	Group Art Unit:	Not yet assigned
Application No.:	Not yet assigned	Examiner:	Not yet assigned
Filed:	August 29, 2001	Att'y Dkt. No.:	58772.000004
Title:	PLASTICIZED BONE AND SOFT TISSUE GRAFTS, AND METHODS OF MAKING AND USING SAME		

**REQUEST BY APPLICANTS FOR INTERFERENCE
PURSUANT TO 37 C.F.R. §1.607 AND PRELIMINARY AMENDMENT**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Preliminary to the examination of the above-identified application on the merits, please amend the application identified in caption as follows:

IN THE SPECIFICATION:

Please add the following paragraph prior to the first paragraph at page 1:

CROSS REFERENCE TO RELATED APPLICATIONS

This is a division of Application Serial No. 09/107,459, filed June 30, 1998, which is incorporated herein by reference in its entirety. --

IN THE CLAIMS:

Please cancel claims 1-32 without prejudice or disclaimer

Please add the following new claims:

--33. (New) A method for treating monolithic bone intended for implantation to conserve the mechanical strength of the bone during lyophilization and subsequent

packaging and maintain such strength during the storage of the bone, the method comprising:

- a) contacting the bone with a mechanical strength-conserving amount of at least one biocompatible mechanical strength-conserving agent, said agent being a liquid organic material which is capable of penetrating and remaining in the bone during its lyophilization, packaging and storage;
- b) lyophilizing the bone containing the mechanical strength-conserving agent; and,
- c) packaging the lyophilized bone.

34. (New) A lyophilized monolithic bone implant containing at least one biocompatible mechanical strength-conserving agent, said agent being a liquid organic material which is capable of penetrating and remaining in the bone during its lyophilization, packaging and storage.--

REMARKS

Entry of the foregoing is respectfully requested.

By Virtue of the present Preliminary Amendment, Applicants have endeavored to copy the claims of U.S. Patent No. 6,162,258 for the purposes of provoking an interference. The present Preliminary Amendment is submitted in conjunction with a Request By Applicants For Interference Pursuant to 37 C.F.R. §1.607 wherein the Applicants respectfully request that an interference be declared between the above-identified application and U.S. Patent No. 6,162,258. It will be appreciated that such patent issued on December 19, 2000. Accordingly, the present amendment is in full compliance with 35 U.S.C. §135(b). The information required by 37 C.F.R. §1.607(a) is set forth below under headings which correspond to the subsections of §1.607 to facilitate consideration by the Examiner.

I. IDENTIFICATION OF THE PATENT WHICH INCLUDES SUBJECT MATTER WHICH INTERFERES WITH THE APPLICATION

The patent which includes subject matter which interferes with subject matter claimed in the above-identified application (the "Wolfenbarger application") is U.S. Patent No. 6,162,258 (the "'258 patent"), which issued on December 19, 2000, to Nelson L. Scarborough and Todd M. Boyce for "LYOPHILIZED MONOLITHIC BONE IMPLANT AND METHOD FOR TREATING BONE". The '258 patent issued from U.S. Patent Application Serial No. 09/382,331, filed August 25, 1999, and did not include any claims to priority. Osteotech, Inc., is the assignee named on the face of the '258 patent.

II. PRESENTATION OF PROPOSED COUNTS 1 & 2

The Applicants respectfully submit attached hereto Appendix A which includes proposed counts 1 and 2. Proposed count 1 identically matches claim 1 of the '258 patent. Proposed count 2 identically matches claim 33 of the '258 patent. These claims 1 and 33 comprise all of the independent claims present in the '258 patent.

III. IDENTIFICATION OF THE CLAIMS IN THE '258 PATENT WHICH CORRESPOND TO THE PROPOSED COUNT

Claims 1-32 of the '258 patent are believed to correspond to proposed count 1, and claims 33-40 of the '258 patent are believed to correspond to proposed count 2. As stated above, the proposed counts 1 and 2 identically match claims 1 and 33 of the '258 patent, respectively. These claims 1 and 33 encompass all of the independent claims present in the '258 patent. Accordingly, claims 2-32, which variously depend upon independent claims 1, also are believed to correspond to proposed count 1; claims 34-40, which variously depend upon independent claim 33, also are believed to correspond to proposed count 2.

IV. CLAIMS OF THE WOLFINBARGER APPLICATION WHICH CORRESPOND
TO THE PROPOSED COUNTS

Claim 33 of the Wolfinbarger application is believed to correspond to proposed count 1, and claim 34 of the Wolfinbarger application is believed to correspond to proposed count 2. Claims 33 and 34 of the Wolfinbarger application identically match claims 1 and 33 of the '258 patent, and both proposed counts, respectively. To assist the Examiner in the consideration of the Request for Interference, the Applicants respectfully submit attached hereto Appendix B which includes a chart providing an element-by-element recitation of claims 33 and 34 of the Wolfinbarger application and an indication of the passages in the originally filed U.S. Application Serial No. 09/107,459, where, at the very least, the newly added claims find support.

As shown in Appendix B, the Wolfinbarger application includes support for the lyophilized monolithic bone implant containing at least one biocompatible mechanical strength-conserving agent, and the method of treating monolithic bone intended for implantation to conserve the mechanical strength of the bone during lyophilization and subsequent packaging. This support can be found throughout the Wolfinbarger application, including Examples 1-10, on pages 22-44.

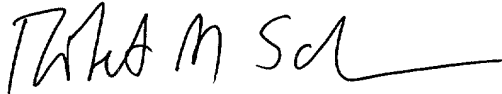
Additionally, the Applicants respectfully submit that the requirements of 35 U.S.C. §135(b) are met because the '258 patent issued on December 19, 2000, and the above-identified divisional application endeavors to copy the independent claims 1 and 33 of the '258 patent within one year of its date of issuance.

V. CONCLUSION

The Applicants respectfully request that an interference be declared employing the proposed counts 1 and 2, set forth on attached Appendix A, with claims 1-32 and 33-40 of the '258 patent, and claims 33 and 34 of the above-identified Wolfinbarger application designated as corresponding to the proposed counts, respectively. Such action is respectfully requested.

In the event that the Examiner has any questions concerning this Request By Applicants For Interference Pursuant to 37 C.F.R. §1.607 and Preliminary Amendment, or the above-identified application in general, the Examiner is invited to contact the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,
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APPENDIX A: PROPOSED COUNTS 1 & 2

1. A method for treating monolithic bone intended for implantation to conserve the mechanical strength of the bone during lyophilization and subsequent packaging and maintain such strength during the storage of the bone, the method comprising:
 - a) contacting the bone with a mechanical strength-conserving amount of at least one biocompatible mechanical strength-conserving agent, said agent being a liquid organic material which is capable of penetrating and remaining in the bone during its lyophilization, packaging and storage;
 - b) lyophilizing the bone containing the mechanical strength-conserving agent; and,
 - e) packaging the lyophilized bone.
2. A lyophilized monolithic bone implant containing at least one biocompatible mechanical strength-conserving agent, said agent being a liquid organic material which is capable of penetrating and remaining in the bone during its lyophilization, packaging and storage.

**APPENDIX B: APPLICATION OF PROPOSED COUNT TO
THE DISCLOSURE OF THE WOLFINBARGER APPLICATION**

Proposed Counts for Interference	Wolfinbarger Application
Count	Claim or Textual Support
<p>U.S. Patent No. 6,162,258</p> <p>1. A method for treating monolithic bone intended for implantation to conserve the mechanical strength of the bone during lyophilization and subsequent packaging and maintain such strength during the storage of the bone, the method comprising:</p> <p>a) contacting the bone with a mechanical strength-conserving amount of at least one biocompatible mechanical strength-conserving agent, said agent being a liquid organic material which is capable of penetrating and remaining in the bone during its lyophilization, packaging and storage;</p> <p>b) lyophilizing the bone containing the mechanical strength-conserving agent; and,</p> <p>c) packaging the lyophilized bone.</p>	<ul style="list-style-type: none"> • Treating a monolithic bone intended for implantation to conserve mechanical strength during lyophilization and subsequent storage is described at least at pages 18-22, which describe plasticization of implants and transplantation into a patient, and Examples 1-10, pages 22-44. • Contacting the bone with a biocompatible mechanical strength-conserving agent is described at least as set forth above and at pages 18-22, which describes methods of plasticization, more specifically, page 20, which describes methods of introducing plasticizers to the bone implant, page 11, which describes methods of incubating, pages 13-15, which describes plasticizers, and Examples 1-10, pages 22-44. • Lyophilizing the bone implant containing a mechanical strength-conserving agent and subsequent packaging is described at least as set forth above, and again in Examples 1-10.
<p>U.S. Patent No. 6,162,258</p> <p>33. A lyophilized monolithic bone implant containing at least one biocompatible mechanical strength-conserving agent, said agent being a liquid organic material which is capable of penetrating and remaining in the bone during its lyophilization, packaging and storage.</p>	<ul style="list-style-type: none"> • See at least above and pages 8-9, lines 20-9, page 10, lines 10-21, and Examples 1-10.

Approved for filing